DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

May 6, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Warning Letter
CIN-WL-02-13413-0

Constandinos C. Samarellis, President
C.E. Foods, Inc.
2652 East 37th Street
Cleveland, Ohio 44115

Dear Mr. C. Samarellis:

We inspected your firm located at the above address on February 19-21, and 26, 2002 and March 20 and 25, 2002 and found that you have serious deviations from the Seafood HACCP regulations, Title 21 Code of Federal Regulations (CFR), Part 123. These deviations cause your frozen, fresh, and ready-to-eat seafood products, e.g., tuna, Mahi-Mahi, salmon, and pasteurized canned crabmeat to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links on the Internet in FDA's home page at www.fda.gov.

You must have a HACCP plan that lists the critical limits that must be met in order to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for precooked seafood products such as pasteurized canned crabmeat is not adequate to control the food safety hazards of pathogen growth and toxin formation. The critical limit for receiving and shipping temperature for pre-packaged seafood products such as the crabmeat is listed as 45^0 F, which is above the recommended temperature of 40^0 F. Your firm must assure that the products you receive and distribute have been adequately cooled during transport to prevent pathogen growth.

You must implement the monitoring procedures listed in your HACCP plan as required by 21 CFR 123.6(b). However, your firm did not adequately monitor any of your seafood products. There is no documentation that the thermometer used to take the temperature of your firm's seafood products is calibrated. In addition, critical control points (CCP) in your firm's HACCP plan are not being monitored in accordance with the frequency listed in the plan for pre-packaged products, semi-processed seafood products, whole fresh seafood products, and raw molluscan shellfish and lobster products. For example, there was no record for the receiving temperature of fresh tuna that was received on 2/13/02 and was subsequently returned to the supplier. In addition, no weekly review of the CCP monitoring is being done as required by your HACCP plan.

You must take appropriate corrective action when a deviation from a critical limit occurs in accordance with 21 CFR 123.7(a). Your firm took a corrective action when it determined that a lot of fresh tuna received on 2/13/02 was unfit for use by returning it to the supplier. However, no further action appears to have been taken. When a critical limit at receipt is violated for seafood products that may be subject to scombrotoxin (histamine) formation as a result of time/temperature abuse, the supplier or carrier should not be used again until evidence is obtained that their transportation practices have changed.

You must have sanitation control records that document monitoring and corrections in order to comply with 21 CFR 123.11(c). Your firm did not maintain adequate sanitation control records for protection of food contact surfaces from adulteration. Adequate measures are not being taken to ensure that bleach used as a sanitizer is used at the proper concentration. Mildew was observed around the ice machine door. Ice from this machine is used daily on your firm's seafood products.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result in enforcement action such as seizure and/or injunction without further notice.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Your response should also outline the specific things you are doing to correct your Seafood HACCP deviations. You may wish to include in your response documentation such as corrected HACCP plans, test results, and/or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097.

Sincerely,

Henry L. Fielden

Henry L. Fielden
District Director
Cincinnati District